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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER
DIETERLE, JENNIFER M

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/539,421	YAMAOKA, HIDEAKI
	Examiner	Art Unit	
	Jennifer Dieterle	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>7/26/10</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1,4 and 7-20</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1,4 and 7-20</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>09 June 2009</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☒ All   b)☐ Some * c)☐ None of:

       1.☒ Certified copies of the priority documents have been received.

       2.☐ Certified copies of the priority documents have been received in Application No. _____.

       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____ .

DETAILED ACTION

Status of the Claims

Claims 2, 3, 5 and 6 have been canceled.

Claim 20 has been added by amended.

Claims 1, 4 and 7-20 are being addressed in this action.

Response to Arguments

Applicant's arguments with respect to claims 1, 4 and 7-18, filed 6/9/2009, have been fully considered but they are not persuasive. Additionally, applicant's newly added claim 20 and amended claim 19 appear to incorporate current dependent claims 17 and 10 respectively. Claims 10 and 17 were rejected in the office action dated 2/25/10 and are being maintained.

1.   Applicant again responds that Gotoh (US 6,071,391) is silent in regards to an electron release region and this response is not persuasive. As previously noted, it is well known in the glucose sensor art that a glucose sensor basic function is to supply a current and when the reduction mediator comes within a range of the working electrode it releases electrons and the reaction based on the mediator allows for the measurement of the concentration of the analyte of interest (Applicants' specification paragraph [0004] discusses background art disclosing the basic known function of a

glucose sensor). Therefore, to be operational, Gotoh inherently has an "electron release" region as do all glucose sensors including those of Hodges and Heller.

2.   Applicant next remarks that the reaction space in Gotoh is between 100-500 micrometers (col. 7, lines 24-32); however, it is noted that there is no specific spacing required in claim 1, all that claim 1 requires is an electron release region which is taught in Gotoh (see above numeral 1). As noted in the office action dated 2/25/10, in view of Gotoh's et al. general description (see col. 3, lines 39-44) of the distance between the surfaces being 100µm - 500µm, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II).

Additionally, as noted in the previous office action, Hodges teaches an electrochemical sensor in which the closest edges of electrodes 52 and 54 are maintained at less than 500 micrometers apart, preferably less than about 450, 400, 350, 300, or 250 micrometers apart, more preferably less than about 200, 150, or 100 micrometers apart, and most preferably less than about 90, 80, 70, 60, 50, **40, 30, 25, 20,** 15, 10, 5 or 1 **micrometers** (col. 7, lines 28-45). Additionally, one or both of

electrodes 52 and 54 may be placed on an additional layer. The spacing being selected

to maintain the separation of the electrodes, thereby providing a sample reservoir in the

electrochemical cell that has a smaller volume of space which facilitates a

corresponding higher amplification factor (page 7, lines 28-31). The facing distance in

Hodges is between the upper substrate/spacer and the electrodes (see figure 2) and

can be optimized by spacer layer 60 being placed within 1 micrometer of the electrodes

which would make the facing distance between the upper surface and the electrode

surface being no greater than the thickness of the electron release region.

Also, Heller et al. also teach a small volume electrochemical sensor for the

determination of glucose (abstract) in which the measurement zone is less than

preferably about **0.05 mm (50 micrometers)**(col. 10, lines 50-54). Heller et al. teach

that a small reaction chamber is preferable because the thickness is small to promote

rapid electrolysis of the analyte, as more of the sample will be in contact with the

electrode surface for a given sample volume. In addition, a thin sample chamber helps

to reduce errors from diffusion of analyte into the measurement zone from other

portions of the sample chamber during the analyte assay, because diffusion time is long

relative to the measurement time. (col. 10, lines 38-54).

Therefore, when Gotoh is taken in view of Heller or Hodges, it is well known to

one skilled in the art to select/optimize a reaction chamber size based on the desire to

reduce errors from diffusion of analyte into the measurement zone from other portions

of the sample chamber during the analyte assay, because diffusion time is long relative

to the measurement time (Heller et al. col. 10, lines 38-54) or to use a smaller volume of

space which facilitates a corresponding higher amplification factor (Hodges page 7, lines 28-31) depending on the outcome desired.

Therefore, applicant's remarks concerning that Gotoh's facing distance is to large are unpersuasive taken in light of the secondary art of record, the fact that one skilled in the art would be motivated to optimize the distance, and that claim 1 does not provide any explicit spacing size. Additionally, the spacing size utilized by applicant in their specification is between 25 and 45 micrometers (see claim 4) which is taught by both Heller and Hodges (see numeral 1 above).

3.   Applicant again presents the argument concerning Hodges being silent as to a thickness of the electron release region above electrode 32, applicant is directed to numeral 1 above and the rejection which notes that electrodes 52 and 54 are located on the same plane and have an electron release region above these electrodes that can be less than 45 micrometers (col. 7, lines 28-45).

4.   With regard to Applicants' argument that Heller is silent as to spacing, col. 10, lines 38-54, teach diffusion into a measurement zone, while analyte may enter through diffusion, this section also teach that the thickness (i.e. height or spacing between the first and second regions) is preferably less than 0.05mm as noted above in the rejection of claim 1. The zone in which the measurement takes place would be the area in which the chemical reaction proceeds which would be where electrons are released.

5.   Applicant also remarks that blood temperature and the hematocrit value will have

less of an effect on the measurement when the facing distance between the electrodes

is no greater than the thickness of the electro release region and that neither Gotoh,

Heller or Hodges contemplates these advantages and that one would not consider their

combination. First, since both Gotoh, Heller and Hodges all teach glucose sensors (see

numeral 2 above), one skilled in the art would be motivated to review all literature in the

art of glucose sensors and to utilize beneficial components or teachings from the

various arts to improve upon. Second, while Gotoh, Heller and Hodges may not fully

recite the benefits sought by applicant, there is motivation to combine them as noted

below in the 103(a) rejections. The fact that applicant has recognized one advantage

does not negate the combination of the references cited and combined below in which a

logical benefit of combining would flow therefrom. Ex parte Obiaya, 227 USPQ 58, 60

(Bd. Pat. App. & Inter. 1985); MPEP 2145 II.

6.   Applicant's remaining arguments regarding claim 4 and 7-19 all recite that since

these claims depend from claim 1, the same arguments would apply; however, as noted

above these arguments are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7.   Claims 1, 4, 7, 8, 12, and 18 are rejected under 35 U.S.C. 103(a) as being

obvious over Gotoh et al. (U.S. Pat. No. 6,071,391) in view of Hodges (WO

2003/032411) or Heller (US 6,143,164).

Regarding claims 1 and 4, Gotoh et al. teaches a thin analysis tool for measuring

glucose comprising:

- a first plate 2 formed with a first 3 and second 4 electrodes (figure 15, col.

    1, lines 62-63; col. 16, lines 33-35);

- a second plate facing the first and second electrodes of the first plate (col.

    1, lines 59-67);

- a reaction space for holding a sample liquid 5 (figure 15);

- a reagent portion that dissolves when the sample is held in the space (col. 14, lines 45-60); the first and second surfaces face each other (col. 17, lines 17-19) spaced at a distance;

- a voltage is applied between the electrodes to facilitate the redox reaction which will inherently create a region around the electrode in which electrons are released (col. 15, line 62).

While Gotoh et al. does not specifically utilize the term "electron release region", it is well known in the glucose sensor art that a glucose sensor basic function is to supply a current and when the reduction mediator comes within a range of the working electrode it releases electrons and the reaction based on the mediator allows for the measurement of the concentration of the analyte of interest (Applicants' specification at paragraph [0004] discusses background art disclosing the basic known function of a glucose sensor). Therefore, to be operational, Gotoh has an "electron release" region as do all glucose sensors.

While Gotoh et al. does teach a reaction space, Gotoh et al. does not specifically teach that the reaction space is no greater than the thickness of the electron release region. Specifically, the facing distance is between 25 and 45 micrometers (claim 4).

Hodges teaches an electrochemical sensor comprising multiple electrodes and a mediator for the determination of analyte (glucose) in a sample (page 3, lines 13-20; figure 2). Hodges teaches a spacer layer 60 and this layer can be placed sufficiently

close to electrodes 52 and 54 such that the closest edges of electrodes 52 and 54 are

maintained at less than 500 micrometers apart, preferably less than about 450, 400,

350, 300, or 250 micrometers apart, more preferably less than about 200, 150, or 100

micrometers apart, and most preferably less than about 90, 80, 70, 60, 50, **40, 30, 25,

20,** 15, 10, 5 or 1 **micrometers** (col. 7, lines 28-45). Additionally, one or both of

electrodes 52 and 54 may be placed on an additional layer. The spacing being selected

to maintain the separation of the electrodes, thereby providing a sample reservoir in the

electrochemical cell that has a smaller volume of space which facilitates a

corresponding higher amplification factor (page 7, lines 28-31). The facing distance in

Hodges is between the upper substrate/spacer and the electrodes (see figure 2) and

can be optimized by spacer layer 60 being placed within 1 micrometer of the electrodes

which would make the facing distance between the upper surface and the electrode

surface being no greater than the thickness of the electron release region.

         Heller et al. also teach a small volume electrochemical sensor for the

determination of glucose (abstract). Heller et al. teach a measurement zone is

contained within this sample chamber and is the region of the sample chamber that

contains only that portion of the sample that is interrogated during the analyte assay.

(col. 9. lines 62-67). Heller et al. teach that the measurement zone is less than

preferably about **0.05 mm (50 micrometers)**(col. 10, lines 50-54). Heller et al. teach

that a small reaction chamber is preferable because the thickness is small to promote

rapid electrolysis of the analyte, as more of the sample will be in contact with the

electrode surface for a given sample volume. In addition, a thin sample chamber helps

to reduce errors from diffusion of analyte into the measurement zone from other

portions of the sample chamber during the analyte assay, because diffusion time is long

relative to the measurement time. (col. 10, lines 38-54).

Therefore, it would have been obvious to one skilled in the art to modify the

reaction chamber size of Gotoh et al. so that the reaction space is no greater than the

thickness of the electron release region, specifically between 25 and 45 micrometers, as

taught by Hodges or Heller et al. because a smaller volume of space which facilitates a

corresponding higher amplification factor (Hodges page 7, lines 28-31) and a smaller

chamber will help to reduce errors from diffusion of analyte into the measurement zone

from other portions of the sample chamber during the analyte assay, because diffusion

time is long relative to the measurement time. (Heller et al. col. 10, lines 38-54).

Additionally, in view of Gotoh's et al. general description (see col. 3, lines 39-44)

of the distance between the surfaces being 100µm - 500µm, it is not inventive to

discover the optimum or workable ranges by routine experimentation. "[W]here the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover

the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d

454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a

known result effective variable, without producing any new or unexpected result, is

within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ

215 (CCPA 1980)(see MPEP § 2144.05, II). As taught above by Heller et al. and

Hodges, it is well known in the art to select/optimize a reaction chamber size based on

the desire to reduce errors from diffusion of analyte into the measurement zone from

other portions of the sample chamber during the analyte assay, because diffusion time

is long relative to the measurement time (Heller et al. col. 10, lines 38-54) or to use a

smaller volume of space which facilitates a corresponding higher amplification factor

(Hodges page 7, lines 28-31) depending on the outcome desired.

Therefore, it would have been obvious to a person of ordinary skill in the art to

select an appropriate distance between the electrodes of Gotoh et al. to establish the

size of the reaction chamber.

Regarding claim 7, Gotoh et al. teaches a thin analyzing device but does not

expressly teach the use of capillary force to move the sample.

However, it is well known in the glucose sensor art that analyte in a glucose

sensor is moved by capillary force. Heller et al. teach that either capillary action is the

known way to move analyte in a sensor and also teach that a sorbent material can be

used to facilitate the uptake of small volume samples by a wicking action and may

complement (or even replace) the capillary action of the sample chamber (col. 10, lines

55-60).

Hodges teaches that a sample to be admitted to the sensor can be drawn in by

wicking or capillary action (page 10, lines 23-24).

Therefore, it would have been obvious to one of ordinary skill in the art to that the

analyte in Gotoh et al. is moved by capillary forces as taught by Heller et al. or Hodges

because capillary force provides for the movement of fluid into a sensor and the force

may even be further enhanced by the use of sorbent material.

Regarding claim 8, Gotoh et al. teaches that the reagent portion includes an

electron mediator and a redox enzyme (col. 4, lines 6-16).

Regarding claim 12, Gotoh et al. teaches that the redox enzyme has glucose

dehydrogenation activity (col. 7, lines 11-13).

Regarding claim 18, Gotoh et al. teach thin analysis tool for measuring glucose

(col. 1, lines 38-40). Gotoh et al. teach the device can be used for the measuring of

blood sugar or urine (col. 13, lines 44-46).

8.   Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et

al. (U.S. Pat. No. 6,071,391) and Hodges (WO 2003/032411) or Heller (US 6,143,164),

as applied to claim 8 above, in further view of Leong et al. (U.S. Pat. No. 6,837,988).

Regarding claim 9, Gotoh et al. teaches a thin analyzing device, but does not

teach the use of ruthenium as the electron mediator.

Leong et al. recognizes that a ruthenium compound can be used as a mediator

agent (col. 11, lines 50-60).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin,* 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07).   The simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR International Co. v. Teleflex Inc.,* 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143 B)

Therefore, it would have been obvious to one of ordinary skill in the art to have substituted the known functionally equivalent ruthenium compound taught by Leong et al. for the electron mediator of Gotoh et al. because Loeng et al. shows that either ruthenium complexes or ferricyanide may be utilized as mediator agents (col. 11, lines 50-60).

9.   Claims 10, 11, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. (U.S. Pat. No. 6,071,391) and Hodges (WO 2003/032411) or Heller (US 6,143,164) and Leong et al., as applied to claim 9 above, in view of Nagakawa et al. (WO 03/025558, with reference to it English equivalent, U.S. Pat. No. 7,390,391).

Regarding claims 10, 11 and 13-17, Gotoh et al. teach a thin analyzing device as noted above and incorporating the items listed in claim 1 above, but do not teach that the X in the ruthenium compound could be NH_3, a halogen ion, CN, pyridine, nicotinamide, or H_2O and that n^+ is the valence of an oxidized Ru(III) complex determined by a type of X. In addition, Gotoh et al. do not teach that the molecular weight of cytochrome C is about 43 kDa and the subunit of glucose dehydrogenase has

a molecular weight of about 60 kDa measured by SDS-polyacrylamide gel

electrophoresis.

Nagakawa et al. teach that a ruthenium compound could be NH_3 or a halogen ion

(col. 3, lines 63-67: col. 4, lines 1-4). Nagakawa et al. also teach that the microbe may

belong to the Burkholderia genus (col. 4, line 57). In addition, Nagakawa et al. teach

that the molecular weight of cytochrome C is about 43 kDa (col. 4, lines 43-45) and the

molecular weight of GDH is about 60 kDa (col. 4, lines 38-39). Nagakawa et al. teach

that the new materials reduced background current (col. 2, lines 62-65).

The Courts have held that the selection of a known material, which is based upon

its suitability for the intended use, is within the ambit of one of ordinary skill in the art.

See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the

combination of familiar elements is likely to be obvious when it does no more than yield

predictable results. Furthermore, the simple substitution of one known element for

another is likely to be obvious when predictable results are achieved. See *KSR*

International Co. v. Teleflex Inc., 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007)

(see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have

modified the electron mediator and enzyme of Gotoh et al. to be a ruthenium compound

where X is NH_3 or a halogen ion (belonging to the genus Burkholderia) having the

molecular weight of cytochrome C is about 43 kDa and the molecular weight of GDH is

about 60 kDa as taught by Nagakawa et al. because the new materials reduced

background current (col. 2, lines 62-65).

10.   Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being obvious over

Gotoh et al. (U.S. Pat. No. 6,071,391) in view of Hodges (WO 2003/032411) or Heller

(US 6,143,164), Leong et al. (U.S. Pat. No. 6,837,988), and Nagakawa et al. (WO

03/025558, with reference to it English equivalent, U.S. Pat. No. 7,390,391).

        Regarding claims 19 and 20, Gotoh et al. teaches a thin analysis tool for

measuring glucose comprising:

- a first plate 2 formed with a first 3 and second 4 electrodes (figure 15, col.

  1, lines 62-63; col. 16, lines 33-35);

- a second plate facing the first and second electrodes of the first plate (col.

  1, lines 59-67);

- a reaction space for holding a sample liquid 5 (figure 15);

- a reagent portion that dissolves when the sample is held in the space (col.

  14, lines 45-60); the first and second surfaces face each other (col. 17,

  lines 17-19) spaced at a distance;

- a voltage is applied between the electrodes to facilitate the redox reaction

  which will inherently create a region around the electrode in which

  electrons are released (col. 15, line 62).

        While Gotoh et al. does not specifically utilize the term "electron release region",

it is well known in the glucose sensor art that a glucose sensor basic function is to

supply a current and when the reduction mediator comes within a range of the working

electrode it releases electrons and the reaction based on the mediator allows for the

measurement of the concentration of the analyte of interest (Applicants' specification at

paragraph [0004] discusses background art disclosing the basic known function of a

glucose sensor). Therefore, to be operational, Gotoh has an "electron release" region

as do all glucose sensors.

    While Gotoh et al. does teach a reaction space, Gotoh et al. do not specifically

teach:

- that the reaction space is no greater than the thickness of the electron

    release region. (Specifically, the facing distance is between 25 and 45

    micrometers (see claim 4));

- the use of a ruthenium mediator (however, Gotoh does teach the use of

    ferricyanide);

- that the X in the ruthenium compound could be NH_3, a halogen ion, CN,

    pyridine, nicotinamide, or H_2O and that n^+ is the valence of an oxidized

    Ru(III) complex determined by a type of X; and

- that the molecular weight of cytochrome C is about 43 kDa and the

    subunit of glucose dehydrogenase has a molecular weight of about 60

    kDa measured by SDS-polyacrylamide gel electrophoresis.

    First, Leong et al. recognizes that a ruthenium compound can be used as a

mediator agent (col. 11, lines 50-60).

    The Courts have held that the selection of a known material, which is based upon

its suitability for the intended use, is within the ambit of one of ordinary skill in the art.

See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07).   The simple

substitution of one known element for another is likely to be obvious when predictable

results are achieved. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82

USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143 B)

Therefore, it would have been obvious to one of ordinary skill in the art to have

substituted the known functionally equivalent ruthenium compound taught by Leong et

al. for the electron mediator of Gotoh et al. because Loeng et al. shows that either

ruthenium complexes or ferricyanide may be utilized as mediator agents (col. 11, lines

50-60).

Second, Hodges teaches an electrochemical sensor comprising multiple

electrodes and a mediator for the determination of analyte (glucose) in a sample (page

3, lines 13-20; figure 2). Hodges teaches a spacer layer 60 and this layer can be placed

sufficiently close to electrodes 52 and 54 such that the closest edges of electrodes 52

and 54 are maintained at less than 500 micrometers apart, preferably less than about

450, 400, 350, 300, or 250 micrometers apart, more preferably less than about 200,

150, or 100 micrometers apart, and most preferably less than about 90, 80, 70, 60, 50,

40, 30, 25, 20, 15, 10, 5 or 1 **micrometers** (col. 7, lines 28-45). Additionally, one or

both of electrodes 52 and 54 may be placed on an additional layer. The spacing being

selected to maintain the separation of the electrodes, thereby providing a sample

reservoir in the electrochemical cell that has a smaller volume of space which facilitates

a corresponding higher amplification factor (page 7, lines 28-31). The facing distance in

Hodges is between the upper substrate/spacer and the electrodes (see figure 2) and

can be optimized by spacer layer 60 being placed within 1 micrometer of the electrodes

which would make the facing distance between the upper surface and the electrode

surface being no greater than the thickness of the electron release region.

Heller et al. also teach a small volume electrochemical sensor for the

determination of glucose (abstract). Heller et al. teach a measurement zone is

contained within this sample chamber and is the region of the sample chamber that

contains only that portion of the sample that is interrogated during the analyte assay.

(col. 9. lines 62-67). Heller et al. teach that the measurement zone is less than

preferably about **0.05 mm (50 micrometers)**(col. 10, lines 50-54). Heller et al. teach

that a small reaction chamber is preferable because the thickness is small to promote

rapid electrolysis of the analyte, as more of the sample will be in contact with the

electrode surface for a given sample volume. In addition, a thin sample chamber helps

to reduce errors from diffusion of analyte into the measurement zone from other

portions of the sample chamber during the analyte assay, because diffusion time is long

relative to the measurement time. (col. 10, lines 38-54).

Therefore, it would have been obvious to one skilled in the art to modify the

reaction chamber size of Gotoh et al. so that the reaction space is no greater than the

thickness of the electron release region, specifically between 25 and 45 micrometers, as

taught by Hodges or Heller et al. because a smaller volume of space which facilitates a

corresponding higher amplification factor (Hodges page 7, lines 28-31) and a smaller

chamber will help to reduce errors from diffusion of analyte into the measurement zone

from other portions of the sample chamber during the analyte assay, because diffusion

time is long relative to the measurement time. (Heller et al. col. 10, lines 38-54).

Additionally, in view of Gotoh's et al. general description (see col. 3, lines 39-44)

of the distance between the surfaces being 100µm - 500µm, it is not inventive to

discover the optimum or workable ranges by routine experimentation. "[W]here the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover

the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d

454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a

known result effective variable, without producing any new or unexpected result, is

within the ambit of a person of ordinary skill in the art. See In re Boesch, 205 USPQ

215 (CCPA 1980)(see MPEP § 2144.05, II). As taught above by Heller et al. and

Hodges, it is well known in the art to select/optimize a reaction chamber size based on

the desire to reduce errors from diffusion of analyte into the measurement zone from

other portions of the sample chamber during the analyte assay, because diffusion time

is long relative to the measurement time (Heller et al. col. 10, lines 38-54) or to use a

smaller volume of space which facilitates a corresponding higher amplification factor

(Hodges page 7, lines 28-31) depending on the outcome desired.

Therefore, it would have been obvious to a person of ordinary skill in the art to

select an appropriate distance between the electrodes of Gotoh et al. to establish the

size of the reaction chamber.

The recitation in the claims that "the facing distance spacing that causes diffusion of the electron transport mediator into the electron release region" is the intended use of the sensor. It must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art as described above is capable of performing the intended use. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458,459 (CCPA 1963).

Lastly, Nagakawa et al. teach that a ruthenium compound could be NH_3 or a halogen ion (col. 3, lines 63-67: col. 4, lines 1-4). Nagakawa et al. also teach that the microbe may belong to the Burkholderia genus (col. 4, line 57). In addition, Nagakawa et al. teach that the molecular weight of cytochrome C is about 43 kDa (col. 4, lines 43-45) and the molecular weight of GDH is about 60 kDa (col. 4, lines 38-39). Nagakawa et al. teach that the new materials reduced background current (col. 2, lines 62-65).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See In re Leshin, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See KSR International Co. v. Teleflex Inc., 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have modified the electron mediator and enzyme of Gotoh et al. to be a ruthenium compound where X is NH_3 or a halogen ion (belonging to the genus Burkholderia) having the molecular weight of cytochrome C is about 43 kDa and the molecular weight of GDH is about 60 kDa as taught by Nagakawa et al. because the new materials reduced background current (col. 2, lines 62-65) thus providing for improved detection.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Thursday, 9am to 4pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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JMD
9/1/10
/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1795